OCT 2 3 2000

K002773

Section 5: 510(k) Summary

NeuroMap with Neuro100 510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

Submitter of Premarket Notification:

Nancy C. MacDonald
Sr. Regulatory Associate
Radionics, a Division of Tyco Healthcare, LP
22 Terry Avenue
Burlington, MA 01803
Telephone: (781) 272-1233
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Performance Standards:

No applicable performance standards have been issued under section 514 of the Food, Drug & Cosmetic Act.

Device Name:

NeuroMap with Neuro100

Common Name:

Electroencephalograph

Technological Characteristics:

The technological characteristics of the revised NeuroMap System are the same as those found with the predicate device, with the exception of the addition of the Neuro100 microstimulation module.

Predicate Device:

Radionics NeuroMap™: 510(k) # K981820, dated November 20, 1998.

Intended Use:

The intended use for the NeuroMap is:

> The Radionics NeuroMap™ is intended to be used for recording of neuronal activity, stimulation of neurons and mapping of functional structures during procedures for which neurophysiologic monitoring is required.

Device Description:

The revised NeuroMap System is an upgrade add an additional feature to the original NeuroMap System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2000

Ms. Nancy C. MacDonald
Senior Regulatory Associate
Radionics, Inc.
Tyco Healthcare Group LP
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K002773
Trade Name: NeuroMap with Neuro100
Regulatory Class: II
Product Code: GWQ
Dated: September 1, 2000
Received: September 6, 2000

Dear Ms. MacDonald:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ODE Indications for Use Statement

510(k) Number (if known): K002773

Device Name: NeuroMap with Neuro100

Indications for Use:

The Radionics NeuroMap™ is intended to be used for recording of neuronal activity, stimulation of neurons and mapping of functional structures during procedures for which neurophysiologic monitoring is required.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR § 801.109)

for Mark N Milhorn
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002773